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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,549	11/02/2001	Masahiko Hirose	04558.035002	5660

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EXAMINER

SORKIN, DAVID L

ART UNIT PAPER NUMBER

1723

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,549

Applicant(s)

HIROSE, MASAHIKO

Examiner

David L. Sorkin

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/452,731.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: In the amended paragraph starting one line 18 of page 7, "ultrafilterartion" should read - - ultrafiltration - -.

Appropriate correction is required.

Claim Objections

2. Claim 1 is objected to because of the following informalities: Claim 1 should only have a period at the end of the claim, not after "the amino groups". Appropriate correction is required.
3. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. It is considered that the scope of "wherein the (b) component is at least one ...", recited in claim 5, extends outside the scope of "wherein the (b) component is an ..." recited in claim 4.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 4-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While it is unclear what is being claimed, as discussed below, it is considered that "new matter" has been entered into claim 1.

a. The range " $2 \leq a$ " is not supported by the original specification.

b. " R^3 " being anything other than " $-NH_2$ " is not supported by the original specification.

c. The use of the subscripts a, b, and c to designate relative amounts of monomeric units in any arbitrary order, versus their standard usage in organic chemistry, according to applicant's remarks filed with the preliminary amendment (paper No. 2) is considered "new matter". Applicants have filed an affidavit which states "control of specific monomer sequences is extremely difficult" therefore "one skilled in the art would know that the formulae could not mean polymers with a specific sequence". However, a major purpose of a patent system is to receive applications for that which has never been done before and hence may be considered extremely difficult to do. It would be entirely inappropriate to assume in a patent application that something which appears to be difficult should necessarily be interpreted to be something else which is easier. The examiner also notes that relatively long sequence-specific polymers have been synthesized in the cases of proteins and DNA. Furthermore, the original Formula 1, would have been open to $0\% < a < 100\%$; $0\% \leq b < 100\%$; and $0\% < c < 100\%$, if only relative amounts are referred to. Using the range " $c < 2$ " to indicate $0\% < c < 100\%$ is a difficult interpretation to accept. Finally, in

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applicant's remarks filed with the preliminary amendment (paper No. 2), it is stated that "The value 'a' in the formula has been amended to reflect that a main chain of *polyvinyl alcohol* requires that at least two PVA repeat units be present in the polymer" (emphasis in original), in blatant contradiction to the argument that a, b, and c refer only to relative amounts.

6. Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the following reasons.

a. The specification gives a sole example of how to make a membrane (Example 1). This example could not be understood or repeated by one skilled in the art for the following reasons:

i. It references "Formula 5" which is not provided.

ii. It refers to an aqueous solution of "sodium hydrocarbon". One skilled in the art would ^{not} know what such a solution is.

iii. Apart from not knowing what an aqueous solution of "sodium hydrocarbon" is, the word "hydrocarbon" represents an infinite set of compounds and one would not know which one to select without infinite experimentation.

iv. Assuming, as applicant would like one to assume, that Formula 5 means Formula 4, one would have to decide whether Formula 4 is written

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in a standard organic chemistry sense or, as applicant would wish to be assumed, merely represents a ratio of monomeric units in any order.

v. Further assuming Formula 4 represents ratios of monomeric units, one would not know the molecular weight of the "polyvinyl alcohol-based amine compound" that should be used, because only relative amount of monomers are provided.

b. The sole example is not within the scope of claim 1 for the following reasons:

i. $y = 0$ in the example.

ii. R^3 is not a primary amine in the example (see detained discussion below in the section 112, second paragraph discussion).

iii. R^2 is not "selected from the group consisting of an ether group, an alkylene group and an ester group" in the example (see detained discussion below in the section 112, second paragraph discussion).

c. One skilled in the art would be further confused by the statement "an amine component comprising at least one polyvinyl alcohol-based amine compound having at least two primary and secondary side chain amino groups" presented in combination with formulas exclusive of secondary amines throughout the original specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. In claim 1, it is unclear what is meant by "at least one amino group selected from the group consisting of primary amines" and " R^3 is a primary amine". The terms "amino group" and "amine" are mutually exclusive terms. A "primary amine" must include a carbon atom. The term "amino group" only refers to a nitrogen atom and hydrogen atoms which are bonded to the nitrogen atom, such as " $-NH_2$ ". A primary amine necessarily includes the amino group " $-NH_2$ ". It is unclear whether " R^3 " is required to include a carbon atom, as the phrase " R^3 is a primary amine" would suggest, or whether " R^3 " is required to be " $-NH_2$ ", in which case Formula 1, would necessarily be a primary amine.

10. In claim 1, the meaning of " R^1 is at least one group selected from the group consisting of an ether group, an alkylene group and an ester group" is unclear. An ether group necessarily includes C-O-C, alkylene C=C and ester C-O-C=O. For example, the group corresponding to R^1 in Formula 4 (amended to be Formula 5) is O-C-C, and does not appear to be "selected from the group consisting of an ether group, and alkylene group and an ester group". Because the sole example of the instant specification is not within the scope of claim 1 for this (and other) reasons, the examiner wishes to make certain that applicant has the same understanding of the scope of R^1 as does the examiner.

11. It is unclear whether a, b, c refer to relative amounts of monomeric units in any arbitrary order (as applicant argues) or their standard usage in organic chemistry.

Conclusion

12. Applicant's arguments and the affidavit of Osami Tozawa are fully addressed in the body of the rejection above.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 8:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David Sorkin

January 22, 2002


W. L. WALKER
SUPERVISORY PATENT EXAMINER
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